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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,922	01/15/2002	Kari Alitalo	28967/37084A	3363

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MARSHALL, GERSTEIN & BORUN LLP
6300 SEARS TOWER
233 S. WACKER DRIVE
CHICAGO, IL 60606

EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,922	ALITALO ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

II. Claims 1-74 are pending.

Election/Restrictions

III. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-38, drawn to a specific isolated peptide, a peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises the same peptide, a composition comprising said peptide, classified in Class 424, subclass 185.1; Class 514, subclass 38.

2. Claims 34-35, 37 and 38, drawn to a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers peptides are different, a composition comprising said peptide, classified in Class 424, subclass 185.1; Class 514, subclass 37.

3. Claims 39-43, 48, 49-58, and 64, drawn to a method of inhibiting the proliferation of a cell *in vivo* using a specific isolated peptide, a peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises the **same peptide**, a method of treating a mammalian subject to modulate the growth in said subject of cells that express VEGFR-3 using said specific peptide, a method of inhibiting metastatic spread of a specific cancer in a mammalian subject using said specific peptide, a method of treating a specific cancer using said specific peptide, a method of treating a specific pathology using said specific peptide, classified in Class 424, subclass 185.1; Class 514, subclass 38.

4. Claims 39-43, 48, 49-58, and 64, drawn to a method of inhibiting the proliferation of a cell *in vivo* using a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers peptides are **different**, a method of treating a mammalian subject to modulate the growth in said subject of cells that express VEGFR-3 using said specific peptide, a method of inhibiting metastatic spread of a specific cancer in a mammalian subject using said specific peptide, a method of treating a specific cancer using said specific peptide, a method of treating a specific pathology using said specific peptide, classified in Class 424, subclass 185.1; Class 514, subclass 37.

5. Claims 39-43, and 47, drawn to a method of inhibiting the proliferation of a cell *in vitro* using a specific isolated peptide, a peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises the **same peptide**, classified in Class 435, subclass 7.23.

6. Claims 39-43, and 47, drawn to a method of inhibiting the proliferation of a cell in vitro using a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers peptides are different, classified in Class 435, subclass 7.23; Class 514, subclass 37.

7. Claims 44-47, drawn to a method of inhibiting the proliferation of a cell *in vitro* using a nucleotide sequence encoding a specific isolated peptide, a peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises the same peptide, classified in Class 435, subclass 6.

8. Claims 44-47, drawn to a method of inhibiting the proliferation of a cell *in vitro* using a nucleotide sequence encoding a specific isolated peptide, a peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises different peptides, classified in Class 435, subclass 6.

9. Claims 44-46, 48, and 59-63, drawn to a method of inhibiting the proliferation of a cell *in vivo* using a **nucleotide sequence** encoding a specific isolated peptide, a peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises the **same peptide**, a method of treating a mammalian subject having a specific disease or a specific cancer using said specific nucleotide sequence, classified in Class 514, subclass 44.

10. Claims 44-46, 48, and 59-63, drawn to a method of inhibiting the proliferation of a cell *in vivo* using a **nucleotide sequence** encoding a specific isolated peptide, a peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises **different peptides**, a method of treating a mammalian subject having a specific disease or a specific cancer using said specific nucleotide sequence, classified in Class 514, subclass 44.

11. Claims 65-67, drawn to a method of screening a biological sample for VEGFR-3 using a specific peptide or a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises the **same peptide**, Classified in Class 435, subclass 7.92

12. Claims 65-67, drawn to a method of screening a biological sample for VEGFR-3 using a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises **different peptide**, Classified in Class 435, subclass 7.92

13. Claims 68-71, drawn to a method of imaging cells that express VEGFR-3 using a specific peptide or a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises the **same peptide**, Classified in Class 435, subclass 7.1

14. Claims 68-71, drawn to a method of imaging cells that express VEGFR-3 using a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises **different peptide**, Classified in Class 435, subclass 7.1

15. Claims 72-74, drawn to a method of screening for neovascularization in a tumor using a specific peptide, or a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises the **same peptide**, Classified in Class 435, subclass 7.1

16. Claims 72-74, drawn to a method of screening for neovascularization in a tumor using a specific peptide, or a specific peptide dimer comprising first and second peptide monomer wherein the first and second peptide monomers comprises **different peptides**, Classified in Class 435, subclass 7.1

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different products as claimed differ with respect to their structure, and physiochemical properties. Therefore, they are patentably distinct.

Inventions of Groups 3-16 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of inhibiting the proliferation of cells, the method of treating distinct disease, the method of screening, imaging using distinct products such as peptide and nucleic acid differs with respect to their process steps and therapeutic endpoints. Therefore, they are patentably distinct.

Inventions of Group (1-2) and Groups (3-16) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in different methods as claimed. Therefore, they are patentably distinct.

IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

V. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121 to elect:

If Group 1, 2, 5, 6, 7, 8, 11, 12, 13, 14, 15 or 16 is elected, the Applicant is required to elect a specific peptide or a specific combination of peptide for the dimer comprising **the specific SEQ ID NOS** such as the ones recited in claims 13, 14, 15, 16, 17, 19, and 20. These peptides differ with respect to their structures and physiochemical properties. Therefore, they are patentably distinct.

If Group 3, 4, 9 or 10 is elected, the Applicant is required to elect a specific peptide or a specific combination of peptide for the dimer comprising **the specific SEQ ID NOS** such as the ones recited in claims 13, 14, 15, 16, 17, 19, and 20, **and a specific disease** such as the ones recited in claim 63. These peptides differ with respect to their structures and physiochemical properties. These diseases differ with respect to their etiology and treatment endpoints. Therefore, they are patentably distinct.

VI. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 34, 39, 44, 49, 59, 64, 65, 68 and 72 are generic.

VII. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

VIII. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

IX. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

X. Due to the complexity of the claimed invention an oral restriction was not made.

XI. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

XII. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

XIII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

VIV. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
December 29, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600